

REMARKS

The first two Forms PTO-1449 submitted in this case have not been signed or initialed. These Forms PTO-1449 were submitted with the original response to the Office Action of September 11, 2003, and Applicants request that they be initialed, signed and returned to indicate that the references listed in those forms have been considered by the Examiner.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 1-3, 5-8, 10-18 and 45-47

Amended claim 1 claims "creating at least one point of entry into the thoracic cavity; gaining access to a distal anastomotic site; inserting a tool through at least one point of entry, said tool including an anvil; inserting said anvil through the wall of a target vessel into the lumen of the target vessel; and performing a distal anastomosis between an end of the graft vessel and the side of the target vessel with said tool while the heart is beating."

In contrast, U.S. Pat. Application No. 2003/0010346 to Paolitto ("Paolitto"), U.S. Pat. No. 5,735,290 to Sterman ("Sterman") and U.S. Pat. No. 6,110,187 to Donlon ("Donlon"), together or separately, do not teach or suggest all of the limitations of amended claim 1. None

of these references, alone or in combination, teach or suggest inserting an anvil through the wall of the target vessel into the lumen of the target vessel and performing a sutureless distal anastomosis between an end of the graft vessel and the side of the target vessel with at least one tool while the heart is beating. In addition, Applicants point out that Paolitto neither teaches nor suggests performing a sutureless distal anastomosis. Rather, Paolitto discloses "[p]erforming a distal anastomosis...with two forceps 91 and one needle holder 93" (paragraph 0183). The forceps "engages and immobilize bypass graft BPG while endoscopic needle holder 93 engages suture 97 with bypass graft BPG." (paragraph 0147). Thus, Paolitto expressly discloses a sutured distal anastomosis, and discloses no other methods, mechanisms or structures for performing a distal anastomosis.

Additionally, Sterman neither teaches nor suggests performing distal or proximal anastomosis while the heart is beating. Instead, the method of Sterman requires that the heart be stopped before anastomosis is performed, in direct contradiction to what is claimed in amended claim 1:

it is necessary to place the patient on cardiopulmonary bypass and to induce cardioplegia (*i.e.*, stop cardiac contraction) prior to connecting the arterial graft to the coronary artery. (column 9, lines 40-43). (emphasis added).

That is, in the procedure of Sterman, the heart must be stopped before anastomosis is performed. The heart is restarted after anastomosis is complete. (column 14, lines 44-46). Sterman not only fails to disclose performing anastomosis while the heart is beating, but also teaches away from performing anastomosis while the heart is beating. For example, Sterman provides an extensive disclosure as to the use of an aortic occlusion catheter to confine cardioplegic fluid to the heart and proximal ascending aorta (column 9, lines 51-56), and also gives detailed directions for stopping the heart (column 11, line 36 through column 13,

line 17). Consequently, Sterman neither teaches nor suggests each and every element claimed in claim 1.

The Office Action discusses a "grasper" and "blades" with respect to claim 1. Applicants point out that such elements are not claimed in claim 1, and thus their presence or absence in a particular reference is irrelevant to claim 1. Further, the Office Action states that a grasper inherently provides certain functions, without providing any support for that finding of inherency as required by MPEP 2112.

The Office Action also states that "completing both a distal and a proximal anastomosis between the graft vessel and the two vessels...is well known in the art." Applicants do not acquiesce in this characterization. Indeed, completing both a distal and a proximal anastomosis between the graft vessel and two vessels, while the heart is beating and in a closed-chest procedure, is not well known in the art.

Thus, the cited references alone or in combination neither teach nor suggest the subject matter claimed in claim 1, and Applicants believe claim 1 is in condition for allowance. The Examiner has admitted on the record, in the Office Action of July 11, 2003, that claim 1 is generic. Thus, were it to be allowed, claim 1 would be allowed as to all species identified in this application.

Further, because claims 2, 3, 5-8, 10-18 and 45-47 depend directly or indirectly from claim 1, which is believed to be allowable, claims 2, 3, 5-8, 10-18 and 45-47 are in condition for allowance under MPEP 608.01(n)(III). Nevertheless, in the interest of completeness, rejections of those dependent claims in the Office Action are addressed below.

The Office Action rejected dependent claims 3-7 over Paolitto in view of U.S. Pat. No. 6,066,144 to Wolf ("Wolf"). This rejection also appears to implicitly cite Sterman as well. As stated above, claims 2, 3 and 5-7 depend from independent claim 1, and thus include all the limitations of claim 1. The discussion of Paolitto and Sterman above applies equally here.

Claim 1 claims "performing a sutureless distal anastomosis between an end of the graft vessel and the side of the second target vessel." In contrast, Wolf discloses a stapling device configured and used for side-to-side anastomosis. (e.g., Figures 13-16; column 10, lines 24-67). Thus, the cited references alone or in combination neither teach nor suggest the subject matter claimed in claims 2, 3 and 5-7, and Applicants believe claims 2, 3 and 5-7 are in condition for allowance.

The Office Action rejected dependent claims 14-17 under Sterman alone. As stated above, claims 14-17 depend from independent claim 1, and thus include all the limitations of claim 1. The discussion of Sterman above applies equally here; it is a reference that expressly limits itself to stopped-heart anastomosis, whereas the method of claim 1 is a method for beating-heart surgery. Further, with regard to claim 16, a "handle of the clamp assembly" cannot fairly be characterized as the claimed "distal anastomotic tool." Thus, the cited reference neither teaches nor suggests the subject matter claimed in claims 14-17, and Applicants believe that claims 14-17 are in condition for allowance.

The Office Action rejected dependent claim 10 over Paolitto in view of U.S. Pat. No. 6,475,222 to Berg ("Berg"). As stated above, claim 10 depends from independent claim 1, and thus include all the limitations of claim 1. The Office Action states that "[t]he graft must span the distance of the anastomosis site exactly." This is incorrect. The graft vessel is at least as long as the shortest distance between the two target vessels, but there is no requirement that the graft "must" span the distance exactly, nor any suggestion of this in the cited references or in the present application. The Office Action thus implicitly states that an exact measurement of the graft vessel is inherent in the claimed method, without providing any support for that finding of inherency as required by MPEP 2112. Thus, the cited reference neither teaches nor suggests the subject matter claimed in claim 10, and Applicants believe that claim 10 is in condition for allowance.

REQUEST FOR ALLOWANCE

Allowance of pending claims 1-3, 5-8, 10-18 and 45-47 with regard to all species is respectfully requested. Please contact the undersigned if there are any questions.

Respectfully submitted,



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